

REMARKS

In accordance with the foregoing, pending claims 1, 6, 12 and 14 are herein amended and claims 1-14 are presented for examination on the merits.

The content of this Amendment is intended to place the application in condition for allowance, to raise no new issues regarding patentability and not to require additional searching of the prior art. Applicants aver that the content of this Amendment was not earlier presented because the Examiner has formulated rejections that Applicants have just fully evaluated.

Applicants respectfully request entry and favorable consideration of said amended claims and the remarks presented herein. The following remarks are respectfully submitted.

I. Claim Rejections Under 35 U.S.C. §102(b)

Claims 1-5 stand rejected under 35 USC § 102 as being anticipated by U.S. Pat. No. 5,331,966 to Bennett et al. (Bennett). The Examiner asserts that Bennett:

"discloses the claimed circuit having a means for detecting atrial depolarization by the subcutaneous electrodes on a hermetically sealed case, a means for pacing having a pacing lead into the right ventricle of a heart. Bennett further shows that the lead can be made from unipolar or bipolar leads. (emphasis added)

Applicants respectfully assert that the Examiner has improperly re-characterized the subject matter of pending claim 1. For ease of reference a portion of claim 1 appear immediately below (as amended herein) to show the "means for pacing" element includes additional limitations that cannot be ignored when the Examiner attempts to defeat the claim as not novel.

As is known, a rejection based on lack of novelty (i.e., anticipation) stands traversed if only a single element found in a rejected claim is not found in the single reference cited against each claim. Thus, while additional distinguishing

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features may be found to exist between the claimed invention and Bennett, Applicants only need point out a single distinguishing feature to traverse the rejection. Applicants respectfully traverse the rejection to the extent such rejection may be considered applicable to the amended claims.

"A single prior art reference anticipates a patent claim if it expressly or inherently describes each and every limitation set forth in the patent claim." Trintec Indus. Inc. v. Top-U.S.A. Corp., 63 USPQ2d 1597, 1599 (Fed. Cir. 2002). "Inherent anticipation requires that the missing descriptive material is 'necessarily present,' not merely probably or possibly present, in the prior art." Id. Bennett fails to disclose each and every feature of the claimed invention, as required by 35 U.S.C. § 102(b), and provides no teaching that would have suggested the desirability of modification to include such features. For example, Bennett does not disclose a "means for pacing a ventricle synchronously with each one of said detected plurality of atrial depolarization signals;" as recited in claim 1. On the contrary, the closest Bennett comes to the claimed invention appears to be the following passage:

The events initiating automatic recording of data may include the operation of a dual chamber cardiac pacemaker at its upper rate limit for a sustained number of beats or predetermined period of time, the switching of the pacing mode from an atrial synchronous mode to a rate responsive mode in response to elevated atrial rates, to track the underlying behavior of the heart in a PMT or spontaneous atrial tachycardia, the detection of an arrhythmia in a tachyarrhythmia control device, the delivery of arrhythmia breaking therapies, and the response of the heart to the delivery of a bolus of medication in an automatic drug administration device. Alternatively, a purely diagnostic system may be implanted in order to record the patient's far-field EGM in patient's suffering from recurrent bouts of syncopy which defy diagnosis by external monitoring and control by drug therapies. The remaining Figures depict signal processing circuitry on systems for implementing the concepts of the invention into preferred embodiments thereof. (col. 17, ll.6-25)

However, Bennett does not exclusively detect P-waves with a SEA and seems to deal almost exclusively with recording in RAM portions of EGMs containing events of interest (col 11, ll. 27-28).

With respect to Bennett, Applicants respectfully assert that, as amended, the presently claimed invention differs significantly in that the present invention provides means for detecting atrial depolarization signals *and means for pacing a ventricle synchronously based on SEA-detected atrial depolarization signals (i.e., P-waves)*. Bennett describes and claims diverse ways of collecting EGM signals and storing them for diagnostic purposes, but does not provide any disclosure regarding the specifically and presently claimed atrially synchronous ventricular pacing stimulus or regime based on SEA-detected P-waves. In fact, the preamble of virtually every independent claim of Bennett et al. recites either an "apparatus for monitoring cardiac signals" or a "method for monitoring cardiac signals." Even the final claim (number 29, set forth in Jepson claim format), only recites the patented combination in the context of "detecting capture" of a heart. Since claims 1-5 include the elements recited immediately above, Applicants respectfully assert that this ground of rejection cannot stand. Accordingly, Applicants request the Examiner to withdraw the ground of rejection based on Bennett.

## II. Claim Rejections Under 35 U.S.C. §102(e)

Claims 1-5 stand rejected under 35 USC § 102(e) as being anticipated by U.S. Pat. No. 6,230,059 to Duffin (Duffin). Applicants repeat the above-noted case law and respectfully assert that the present ground of rejection stands traversed if only a single element found in a rejected claim is not found in the single reference cited against said claim. Thus, while additional distinguishing features may be found to exist between the claimed invention and Duffin, Applicants only need point out a single distinguishing feature to traverse the rejection.

Applicants respectfully assert that Duffin, like Bennett, does not disclose or deal with the issue(s) and elements addressed by the presently pending claims. That is, Duffin also deals exclusively with collection (and filtering) of EGM signals and does not disclose the claimed subject matter regarding synchronized pacing of a ventricle based on SEA-sensed P-waves (i.e., atrial depolarizations). As a result, the rejection based wholly on Duffin can be shown to be defective and cannot stand. Accordingly, Applicants respectfully request the Examiner to withdraw this ground of rejection.

### III. Claim Rejections Under 35 U.S.C. §103(a)

Claims 6-11 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Bennett in view of U.S. Pat. No. 4,907,593 to Rapach et al. (Rapach) or U.S. pat. No. 5,489,293 to Pless et al. (Pless).

Applicants incorporate all the prior remarks regarding Bennett as if fully set forth herein. In addition, Applicants have studied the Rapach and Pless references and respectfully assert that the Examiner has failed to lodge a *prima facie* obviousness rejection and therefore this ground of rejection should be withdrawn.

Applicants respectfully traverse the rejections.

In connection with combining references to support an assertion of obviousness, it is well established that the Examiner bears the burden of establishing a *prima facie* case of obviousness. *In re Oetiker*, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992). In doing so, the Examiner must determine whether the prior art provides a "teaching or suggestion to one of ordinary skill in the art to make the changes that would produce" the claimed invention. *In re Chu*, 36 USPQ2d 1089, 1094 (Fed. Cir. 1995). A *prima facie* case of obviousness is established only when this burden is met.

In the case of *In re Lee*, 61 USPQ2d 1430 (Fed. Cir. 2002), the Federal Circuit stated: "This factual question of motivation is material to patentability, and [can] not be resolved on subjective belief and unknown authority." *Id.* at 1434.

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The Court of Appeals for the Federal Circuit has made clear that motivation to combine references must be found in the record, and that it is impermissible hindsight for the Examiner to use the motivation stated in Applicants' own disclosure as a blueprint to reconstruct the claimed invention from the prior art. See Interconnect Planning Corp. v. Feil, 227 USPQ 543 (Fed. Cir. 1985); In re Fine, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988); In re Gorman, 18 USPQ 2d 1885, 1888 (Fed. Cir. 1991); AI-Site Corp. v. VSI International, Inc., 50 USPQ2d 1161, 1171 (Fed. Cir. 1999).

A patentable invention may arise from a combination of elements found in the prior art. It is therefore not sufficient for the Examiner merely to identify individual components of an invention in multiple references. E.g., Ruiz v. A.B. Chance Co., 57 USPQ2d 1161, 1167 (Fed. Cir. 2000). The Examiner must demonstrate that a skilled artisan, with no knowledge of Applicants' claimed invention, would have selected the components for combination in the manner claimed. In re Kotzab, 55 USPQ2d 1313, 1316-18 (Fed. Cir. 2000). It is not sufficient for the Examiner to assert that separate elements of the claimed invention exist in the prior art, or that the elements in different references *could* be combined, or that there is an apparent need for combination of the elements, or that elements may be substitutes for one another. Ruiz v. A.B. Chance Co., 57 USPQ2d at 1167. To establish a *prima facie* case of unpatentability, the Examiner must provide evidence showing a reason, suggestion or motivation to combine.

The Examiner has failed to provide evidence showing a reason, suggestion or motivation to combine Bennett with either Pless or Rapach. The Examiner suggested combining the references, but there is no support in the record for such a suggestion. Nothing in suggests that external electronics would benefit from simplification.

The Examiner's assertion that changing the type of sensor would have been an obvious design choice is incorrect as a matter of law. First, it applies an incorrect legal standard. In a proper obviousness determination, the prior art

must give a reason or motivation for making the claimed invention. E.g., In re Chu, 36 USPQ2d at 1094; In re Oetiker, 24 USPQ2d at 1446. The combination of elements from non-analogous sources, in a manner that reconstructs the Applicants' invention only with the benefit of hindsight, is insufficient to support a *prima facie* case of obviousness. In re Oetiker, 24 USPQ2d at 1446. Where the prior art does not teach that references should be combined to produce the claimed invention, the Examiner cannot cure this deficiency by using words such as "design choice" or "design alternative." In re Chu, 36 USPQ2d at 1094-95.

A bare assertion that an element of a claim is an "obvious design choice" does not support a *prima facie* case of unpatentability. It is merely a conclusory statement, unsupported by the record, and cannot support a *prima facie* case of unpatentability. In re Lee, 61 USPQ2d at 1434-35; In re Dembiczak, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999).

For at least these reasons, the Examiner has failed to establish a *prima facie* case for non-patentability of Applicants' claims 6-11 under 35 U.S.C. § 103(a). Withdrawal of these rejections is requested.

Most notably, it appears that Bennett offers no motivation or suggestion to combine the teaching thereof with either the Rapach alleged relatively lower-defibrillation energy technology or the alleged myopotential-mediated rate responsive pacing techniques of Pless.

For example, Rapach does not appear to relate to or deal with the subject matter of the present invention as implied at least in part by the following excerpt from the Summary section of Rapach:

It is thus an object of the present invention to provide a method and apparatus for delivering a defibrillation shock sequence which requires lower voltage than conventional defibrillation waveforms.

It is another object of the invention to provide a method of defibrillation which delivers lower energy shocks to the heart than conventional techniques.

Likewise, Pless offers nothing to advance the disclosure of the Bennett et al. reference since Pless appears to relate solely to a rat -responsive pacemaker

that utilizes myopotential (i.e., electrical charge due to muscle contractions) to alter the pacing rate of an ambulatory patient. Nothing in Pless appears to relate to or deal with the subject matter addressed by either the Bennett or Rapach. Accordingly, Applicants respectfully request that the Examiner withdraw this ground of rejection.

#### IV. Claim Rejections Under 35 U.S.C. §103(a)

Claims 12-14 stand rejected as being unpatentable over Nigram et al. (WO 00/61225) in view of Bennett or Duffin. Applicants reviewed the Nigram et al. reference and initially noted that the techniques therein appear not to relate to or require a subcutaneous electrode array (SEA) and, therefore there is no linkage between any such SEA and atrial synchronized ventricular pacing, as claimed herein. Applicants previously tendered an amendment to independent claim 12 that added a limitation clearly distinguishing the claim (and claims 13 and 14) from Nigram et al. Namely, Applicants previously added the following claim limitation: "when a P-wave threshold crossing is sensed by at least a pair of electrodes of a subcutaneous electrode array." Applicants respectfully assert that Nigram et al. does not include this claim limitation and therefore the anticipation rejection based on Nigram et al. fails. Accordingly, Applicants respectfully request the Examiner to withdraw the rejection based on Nigram et al.

#### V. CONCLUSION

Applicants respectfully assert that, following entry of the instant Amendment, all pending claims (i.e., claims 1-14) of the present application are in condition for allowance. Applicants respectfully request reconsideration and prompt allowance of all pending claims so that the invention herein claimed may pass to timely issuance as U.S. Letters Patent. Please charge any additional fees or credit any overpayment to deposit account number 13-2546. The

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Examiner is invited to telephone the below-signed attorney to discuss this application if there are any formal matters remaining after this response.

Respectfully submitted,



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